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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,657	02/20/2001	Ulf Landegren	LANDEGREN=1A	5356
1444 7590 02/21/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/21/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/785,657

Applicant(s)

LANDEGREN ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7, 13-15 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7, 13-15 and 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to the office action filed on December 14, 2006 has been considered.

Status of the application

2. Claims 2-7, 13-15, 17-28 are pending. Claims 1, 8-12 and 16 are cancelled. New claim 28 is added. All the arguments and amendment have been fully considered and found persuasive in part for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New issues

Sequence Rules and Objection to the specification

3. The specification are objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least Figure 10 and page 13) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Examiner also notes that the application contains no sequence listing either in the form of a paper copy or in a computer readable form. Appropriate correction is required.

Non-Statutory Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- A. Claims 2-7, 14, 19-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,7, 21, 22 and 26 of U.S. Patent No. 6,511,809 ('809). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is

either anticipated by, or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim 2, 20, 25, 27-28 are generic to all that is recited in claims of the patent '809. That is, the claims 1, 21-22, 26 of the patent '809 fall entirely within the scope of claim 2, 20, 25, 27-28 or in other words, claims 2, 20, 25, 27-28 are anticipated by the claims 1, 21-22, 26 of the patent '809. Specifically the method for detecting the presence of one or more analytes in solution comprising binding two or more proximity probes to a respective binding site on said analyte(s) not immobilized, allowing the binding moiety to bind said analyte(s) and allowing the nucleic acids of the proximity probes to interact with each other, if they are in close proximity to each other and detecting the degree of interaction between the nucleic acids, thereby detecting the presence of one or more analytes in solution is within the scope of the patented claims 1, 21-22, 26 because the patented claims 1, 21-22, 26 encompass solution based embodiment, which are clearly distinguishable by claims 2, 25 of the patent which disclose specifically immobilization of analytes on a solid support. Further, claims 3-7, 13-15, 17-24, 26 are generic to all that is recited in claims 7 of the patent '809. Thus the instant claims encompass the claims in the patent ('809) and are related as genus and species, and are coextensive in scope.

The courts have stated that a genus is obvious in view of the teachings of a species. see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed.Cir. 1989). Therefore the instantly claimed method is obvious over the claims in the patent. Thus the instant claims are rejected under obviousness-type of double patenting.

B. Claims 13, 15, 17-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 21, 22 and 26 of U.S. Patent No. 6,511,809 ('809) in view of *Ebersole et al.* (WO 97/32044). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and the instant claims differ in

that the patented claims do not disclose the use of the method for high throughput screening for ligand-receptor interaction or a method for screening a drug candidate or detection of infectious agents.

Ebersole et al. teach a homogeneous detection probe system which requires detection without immobilization of the analyte/probe, wherein the method comprises probes in close proximity facilitate energy transfer and signal modification of the reporter moieties thereby detecting the signal without any alteration of signal generation potential (see page 17, line 4-31).

Ebersole et al. also teach that the method facilitates detection of analyte directly in solution (see page 17, line 29-31, page 19, line 1-7). Ebersole et al. teach that the method comprises detection of analyte from infectious agents, in food and environment (see page 1, line 14-18); highthroughput assay format for detecting analyte(s) (see page 25, line 35-38).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method for detecting one or more analytes as taught by patent '809 with method for detecting infectious agents or drug candidates, to achieve expected advantage of developing an improved and sensitive high throughput method for detecting specific analytes because Ebersole taught that the invention enables the detection of analyte and also provides real-time detection of the analyte in a high throughput manner (see page 17, line 29-31, page 19, line 1-7). An ordinary practitioner would have motivated to combine the method of patent '809 with the incorporation of a step of detecting specific analytes as taught by Ebersole et al. for purpose of developing a simple inexpensive and real-time sensitive method for detecting analyte(s) in a sample. Therefore the instant claims are rejected under obviousness double patenting.

Response to arguments:

5. Applicants' arguments are fully considered and found persuasive in part. With regard to the inquiry as to who is the first inventor of the subject matter, Applicants' arguments are fully considered and found persuasive. However with regard to the conflicting claims in the patent '809 and the instant invention, Applicants' arguments are found unpersuasive. Applicants argue that the patent '809 disclose claims to solid phase embodiment and the instant claims are drawn to a homogenous embodiment (solution based) and argue that the situation is identical to the previous rejection on record over Landegren in view of Ebersole which disclose solid phase embodiment, for which the Examiner confirmed the withdrawal of the previous rejection in view of the declaration submitted by the applicants

under 1.132 and confirming that the solid phase embodiment is patentable distinct from the homogenous embodiment of the instant invention therefore the '809 patent which discloses solid phase embodiment should be patentable distinct as that of Landegren solid phase embodiment. Applicants' arguments are found unpersuasive regarding the '809 patent. The patented claims in '809 are not solely drawn to solid phase embodiments, rather the patented claims of '809 encompass both solid (claims 2, 25) and homogenous embodiments (claims 1, 21-22, 26) thus the situation is different from that of the previous rejection over Landgren in view of Ebersole therefore the patented claims of '809 are not patentably distinct. To address this Examiner herewith rejects the instant claims under obvious double-patenting.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Prabha Chunduru
SURYAPRABHA CHUNDURU
PRIMARY EXAMINER 2/16/07